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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,694	06/15/2006	Roberto A. Macina	DEX-0549	8350

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EXAMINER	
MUMMERT, STEPHANIE KANE	
ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
11/25/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No.	Applicant(s)	
	10/537,694	MACINA ET AL.	
	Examiner	Art Unit	
	STEPHANIE K. MUMMERT	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *7,10-15,17 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,9 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/6/05*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-6, 8-9 and 16 and SEQ ID NO:12 and SEQ ID NO:13 in the reply filed on August 14, 2009 is acknowledged. The traversal is on the ground(s) that "an elected nucleic acid sequence, as well as the polypeptide encoded thereby and antibodies thereto, share the special technical feature of being useful in diagnosing cancer". This is not found persuasive because the claims of Group I are not limited specifically to the full length nucleic acid sequence or the full length sequence of the protein. Instead, the full scope of Group I also includes "nucleic acid molecule that selectively hybridizes to the nucleic acid molecule of (a) and (b)". Such sequences are well known in the art and due to the breadth of the scope include a variety of sequences that are not particularly related to either the protein or to the antibody directed to the protein. Therefore, the claims are not linked by a special technical feature and therefore Applicant's arguments are not persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7, 10-15 and 17-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 14, 2009.

Claims 1-6, 8-9 and 16 are pending and will be examined.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on June 6, 2005 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8-9 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claims 1 and 16 encompass nucleic acid molecules that selectively hybridize to SEQ ID NO:12, or to the nucleic acid molecule that encodes SEQ ID NO:113, a broad genus of nucleic acids that have not been properly described.

Legal Analysis

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common

attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.).

In the instant case, while claims 1 and 16 are directed to the nucleic acid sequence encoding SEQ ID NO:113, the nucleic acid sequence comprising SEQ ID NO:12 and sequences 95% identical to (a) or (b), claims 1 and 16 also encompass nucleic acid molecules that selectively hybridize to SEQ ID NO:12, or selectively to the nucleic acid molecule that encodes SEQ ID NO:113 that have not been properly described. A large variety of sequences are reasonably capable of hybridizing or which "selectively hybridize" to a nucleic acid sequence of 2297 bases in length. Applicant has taught certain sequences which are useful to detect the mRNA which encodes SEQ ID NO:113 and therefore would hybridize to SEQ ID NO:12. These sequences include SEQ ID NO:233-235, primers and probes useful for Real Time QRT-PCR detection of SEQ ID NO:113 and four probes are generally described as present on a breast array as useful for detection of the mRNA associated with SEQ ID NO:113. However, these seven sequences are not representative of the entire scope of the broad genus of nucleic acids which are capable of selective hybridization. The specification also does not provide guidance regarding what factors influence the selective hybridization, or the length of complementarity necessary between SEQ ID NO:12 and the nucleic acid molecule claimed which would meet the limitation.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

> "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an

> indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of sequences based on the term "selectively hybridizes" without further guidance regarding the stringency of hybridization, the percent complementarity or the length of sequence necessary to meet the limitation leads to a conclusion of lack of proper written description. This is precisely the situation of naming a type of material which is generally known to likely exist, but, except for the specific sequence comprising SEQ ID NO:12, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim.

Absence of a representative number of species

In the current case, the first question is what constitutes a generic claim. In this case, the generic claim includes a broad scope of nucleic acid molecules capable of selective hybridization to SEQ ID NO:12 and to the nucleic acid encoding SEQ ID NO:113. As noted above, at most, Applicant has taught certain sequences which are useful to detect the mRNA which encodes SEQ ID NO:113 and therefore would hybridize to SEQ ID NO:12. These sequences include SEQ ID NO:233-235, primers and probes useful for Real Time QRT-PCR detection of SEQ ID NO:113 and four probes are generally described as present on a breast array as useful for detection of the mRNA associated with SEQ ID NO:113. However, these seven sequences are not representative of the entire scope of the broad genus of nucleic acids which are capable of hybridizing

Absence of any structure-function relationship

The second issue is whether there is any structure function relationship which correlates a

function with a particular structure. This question fundamentally addresses the issue of whether there is any structure which the specification demonstrates is necessarily correlated with the nucleic acid molecules which are capable of selective hybridization. Applicant has provided no sequence which is common to the nucleic acids which fall within the scope of this broad genus of nucleic acids. Since there is no common structure among the nucleic acids that are specifically associated with the unknown function of the nucleic acid, except for a role as a primer or probe, there is no structure-function relationship between the genus of nucleic acids claimed.

Conclusion

In the application at the time of filing, there is no record or description which would demonstrate possession of the genus of nucleic acids capable of selective hybridization to either SEQ ID NO:12 or to the nucleic acid encoding SEQ ID NO:113. Therefore, the claims fail to meet the written description requirement by encompassing a broad genus of nucleic acid molecules which are not properly described in the specification.

Claim Objections

Claim 16 is objected to because of the following informalities: The amendment to the claims changes the claim to state "(e) a polypeptide a polypeptide of claim 12", which repeats the phrase "a polypeptide". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-6, 8-9 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Afar et al. (WO01/31012, published March 5, 2001). Afar teaches a sequence which is upregulated in prostate cancer, 20P2H8, a protein which shares homology with heterogeneous nuclear ribonucleoproteins (hnRNP) (Abstract).

With regard to claim 1, Afar teaches an isolated nucleic acid molecule comprising: (a) a nucleic acid molecule comprising a nucleic acid sequence that encodes an amino acid sequence of SEQ ID NO: 113;

(b) a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 12;

(c) a nucleic acid molecule that selectively hybridizes to the nucleic acid molecule of (a) or (b) (see alignment below, where 20P2H8, which corresponds to SEQ ID NO:1 of Afar shares 85.7% similarity with the full length of SEQ ID NO:12 in the instant claim; see detail regarding SEQ ID NO:1 of Afar at p. 5 and p. 11, for example);

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Qy        317 CATATCTAGGCCTGTCTCCTCCCTCCTACACATTTCCAGCTCCTGCTGCAGTTATTCCTA 376
              ||    | | ||||||||||||||||||||||||||||||||||||||||||||||||
Db       1601 CACCGCCATGCCTGTCTCCTCCCTCCTACACATTTCCAGCTCCTGCTGCAGTTATTCCTA 1660

Qy        377 CAGAAGCTGCCATTTACCAGCCCTCTGTGATTTTGAATCCACGAGCACTGCAGCCCTCCA 436
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1661 CAGAAGCTGCCATTTACCAGCCCTCTGTGATTTTGAATCCACGAGCACTGCAGCCCTCCA 1720

Qy        437 CAGCGTACTACCCAGCAGGCACTCAGCTCTTCATGAACTACACAGCGTACTATCCCAGCC 496
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1721 CAGCGTACTACCCAGCAGGCACTCAGCTCTTCATGAACTACACAGCGTACTATCCCAGCC 1780

Qy        497 CCCCAGGTTCGCCTAATAGTCTTGGCTACTTCCCTACAGCTGCTAATCTTAGCGGTGTCC 556
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1781 CCCCAGGTTCGCCTAATAGTCTTGGCTACTTCCCTACAGCTGCTAATCTTAGCGGTGTCC 1840
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Qy        557 CTCCACAGCCTGGCACGGTGGTCAGAATGCAGGGCCTGGCCTACAATACTGGAGTTAAGG 616
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1841 CTCCACAGCCTGGCACGGTGGTCAGAATGCAGGGCCTGGCCTACAATACTGGAGTTAAGG 1900

Qy        617 AAATTCTTAACTTCTTCCAAGGTTACCAGTATGCAACCGAGGATGGACTTATACACACAA 676
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1901 AAATTCTTAACTTCTTCCAAGGTTACCAGTATGCAACCGAGGATGGACTTATACACACAA 1960

Qy        677 ATGACCAGGCCAGGACTCTACCCAAAGAATGGGTTTGTATTTAAGGGCCCCAGCAGTTAG 736
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1961 ATGACCAGGCCAGGACTCTACCCAAAGAATGGGTTTGTATTTAAGGGCCCCAGCAGTTAG 2020

Qy        737 AACATCCTCAGAAAAGAAGTGTTTGAAAGATGTATGGTGATCTTGAAACCTCCAGACACA 796
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2021 AACATCCTCAGAAAAGAAGTGTTTGAAAGATGTATGGTGATCTTGAAACCTCCAGACACA 2080

Qy        797 AGAAAACTTCTAGCAAATTCAGGGGAAGTTTGTCTACACTCAGGCTGCAGTATTTTCAGC 856
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2081 AGAAAACTTCTAGCAAATTCAGGGGAAGTTTGTCTACACTCAGGCTGCAGTATTTTCAGC 2140

Qy        857 AAACTTGATTGGACAAACGGGCCTGTGCCTTATCTTTTGGTGGAGTGAAAAAATTTGAGC 916
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2141 AAACTTGATTGGACAAACGGGCCTGTGCCTTATCTTTTGGTGGAGTGAAAAAATTTGAGC 2200

Qy        917 TAGTGAAGCCAAATCGTAACTTACAGCAAGCAGCATGCAGCATACCTGGCTCTTTGCTGA 976
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2201 TAGTGAAGCCAAATCGTAACTTACAGCAAGCAGCATGCAGCATACCTGGCTCTTTGCTGA 2260

Qy        977 TTGCAAATAGGCATTTAAAATGTGAATTTGGAATCAGATGTCTCCATTACTTCCAGTTAA 1036
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2261 TTGCAAATAGGCATTTAAAATGTGAATTTGGAATCAGATGTCTCCATTACTTCCAGTTAA 2320

Qy       1037 AGTGGCATCATAGGTGTTTCCTAAGTTTTAAGTCTTGGATAAAAACTCCACCAGTGTCTA 1096
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2321 AGTGGCATCATAGGTGTTTCCTAAGTTTTAAGTCTTGGATAAAAACTCCACCAGTGTCTA 2380

Qy       1097 CCATCTCCACCATGAACTCTGTTAAGGAAGCTTCATTTTTGTATATTCCCGCTCTTTTCT 1156
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2381 CCATCTCCACCATGAACTCTGTTAAGGAAGCTTCATTTTTGTATATTCCCGCTCTTTTCT 2440

Qy       1157 CTTCATTTCCCTGTCTTCTGCATAATCATGCCTTCTTGCTAAGTAATTCAAGCATAAGAT 1216
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2441 CTTCATTTCCCTGTCTTCTGCATAATCATGCCTTCTTGCTAAGTAATTCAAGCATAAGAT 2500

Qy       1217 CTTGGAATAATAAAATCACAATCTTAGGAGAAAGAATAAAATTGTTATTTTCCCAGTCTC 1276
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2501 CTTGGAATAATAAAATCACAATCTTAGGAGAAAGAATAAAATTGTTATTTTCCCAGTCTC 2560

Qy       1277 TTGGCCATGATGATATCTTATGATTAAAAACAAATTAAATTTTAAAACACCTGAAGATAT 1336
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2561 TTGGCCATGATGATATCTTATGATTAAAAACAAATTAAATTTTAAAACACCTGAAGATAA 2620

Qy       1337 ATTAGAAGAAATTGTGCACCCTCCACAAAACATACAAAGTTTAAAAGTTTGGATCTTTTT 1396
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2621 ATTAGAAGAAATTGTGCACCCTCCACAAAACATACAAAGTTTAAAAGTTTGGATCTTTTT 2680

Qy       1397 CTCAGCAGGTATCAGTTGTAAATAATGAATTAGGGGCCAAAATGCAAAACGAAAAATGAA 1456
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2681 CTCAGCAGGTATCAGTTGTAAATAATGAATTAGGGGCCAAAATGCAAAACGAAAAATGAA 2740
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Qy       1457 GCAGCTACATGTAGTTAGTAATTTCTAGTTTGAACTGTAATTGAATATTGTGGCTTCATA 1516
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2741 GCAGCTACATGTAGTTAGTAATTTCTAGTTTGAACTGTAATTGAATATTGTGGCTTCATA 2800

Qy       1517 TGTATTATTTTATATTGTACTTTTTTCATTATTGATGGTTTGGACTTTAATAAGAGAAAT 1576
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2801 TGTATTATTTTATATTGTACTTTTTTCATTATTGATGGTTTGGACTTTAATAAGAGAAAT 2860

Qy       1577 TCCATAGTTTTTAATATCCCAGAAGTGAGACAATTTGAACAGTGTATTCTAGAAAACAAT 1636
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2861 TCCATAGTTTTTAATATCCCAGAAGTGAGACAATTTGAACAGTGTATTCTAGAAAACAAT 2920

Qy       1637 ACACTAACTGAACAGAAGTGAATGCTTATATATATTATGATAGCCTTAAACCTTTTTCCT 1696
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2921 ACACTAACTGAACAGAAGTGAATGCTTATATATATTATGATAGCCTTAAACCTTTTTCCT 2980

Qy       1697 CTAATGCCTTAACTGTCAAATAATTATAACCTTTTAAAGCATAGGACTATAGTCAGCATG 1756
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2981 CTAATGCCTTAACTGTCAAATAATTATAACCTTTTAAAGCATAGGACTATAGTCAGCATG 3040

Qy       1757 CTAGACTGAGAGGTAAACACTGATGCAATTAGAACAGGTACTGATGCTGTCAGTGTTTAA 1816
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       3041 CTAGACTGAGAGGTAAACACTGATGCAATTAGAACAGGTACTGATGCTGTCAGTGTTTAA 3100

Qy       1817 CACTATGTTTAGCTGTGTTTATGCTATAAAAGTGCAATATTAGACACTAGCTAGTACTGC 1876
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       3101 CACTATGTTTAGCTGTGTTTATGCTATAAAAGTGCAATATTAGACACTAGCTAGTACTGC 3160

Qy       1877 TGCCTCATGTAACTCCAAAGAAAACAGGATTTCATTAAGTGCATTGAATGTGGCTATTTC 1936
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       3161 TGCCTCATGTAACTCCAAAGAAAACAGGATTTCATTAAGTGCATTGAATGTGGATATTTC 3220

Qy       1937 TCTAAGTTACTCATATTGTCCTTTGCTTGAATGCAATGCCGTGCAGATTTATGTGGCTGC 1996
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       3221 TCTAAGTTACTCATATTGTCCTTTGCTTGAATGCAATGCCGTGCAGATTTATGAGGCTGC 3280

Qy       1997 TATTTTTATTTTCTGTGCATTACTTTAACACCTTAAAGGGAGAAGCAAACATTTCCTTCT 2056
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       3281 TATTTTTATTTTCTGTGCATTACTTTAACACCTTAAAGGGAGAAGCAAACATTTCCTTCT 3340

Qy       2057 TCAGCTGACTGGCAATGGCCCTTTAACTGCAATAGGAAGAAAAAAAAAAAGGTTTGTGTG 2116
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       3341 TCAGCTGACTGGCAATGGCCCTTTAACTGCAATAGGAAGAAAAAAAAAAAGGTTTGTGTG 3400

Qy       2117 AAAATTGGTGATAACTGGCACTTAAGATCGAAAAGAAATTTCTGTATACTTGATGCCTTA 2176
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       3401 AAAATTGGTGATAACTGGCACTTAAGATCGAAAAGAAATTTCTGTATACTTGATGCCTTA 3460

Qy       2177 AGATGCCCAAAGCTGCCCAAAGCTCTGAAAGACTTTAAGATAGGCAGTAATGCTTACTAC 2236
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       3461 AGATGCCCAAAGCTGCCCAAAGCTCTGAAAGACTTTAAGATAGGCAGTAATGCTTACTAC 3520

Qy       2237 AATACTACTGAGTTTTTGTAGAGTTAACATTTGATAATAAAACTTGCCTGTTTAATCTCA 2296
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       3521 AATACTACTGAGTTTTTGTAGAGTTAACATTTGATAATAAAACTTGCCTGTTTAATCTCA 3580

Qy       2297 A 2297
             |
Db       3581 A 3581
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or (d) a nucleic acid molecule having at least 95% sequence identity to the nucleic acid molecule of (a) or (b).

With regard to claim 2, Afar teaches an embodiment of claim 1, wherein the nucleic acid molecule is a cDNA (Abstract, where 20P2H8 comprises an approximately 3600 bp cDNA sequence which corresponds to SEQ ID NO:1).

With regard to claim 3, Afar teaches an embodiment of claim 1, wherein the nucleic acid molecule is genomic DNA (p. 20, where the sequences include genomic DNA; and 22-23, where the process of isolating a genomic sequence from which the 20P2H8 sequence is expressed is taught).

With regard to claim 4, Afar teaches an embodiment of claim 1, wherein the nucleic acid molecule is an RNA (p. 20, where the sequences include antisense and RNA sequences).

With regard to claim 5, Afar teaches an embodiment of claim 1, wherein the nucleic acid molecule is a mammalian nucleic acid molecule (p. 18, where it is noted that the sequence provided in Figure 1 is a human sequence of 20P2H8).

With regard to claim 6, Afar teaches an embodiment of claim 5, wherein the nucleic acid molecule is a human nucleic acid molecule (p. 18, where it is noted that the sequence provided in Figure 1 is a human sequence of 20P2H8).

With regard to claim 8-9, Afar teaches a vector and host cell comprising the nucleic acid molecule of claim 1 (p. 23, where vectors and host cells which include 20P2H8 sequences are discussed).

With regard to claim 16, Afar teaches a kit for detecting a risk of cancer or presence of cancer in a patient, said kit comprising a means for determining the presence of:

(a) a nucleic acid molecule comprising a nucleic acid sequence that encodes an amino acid sequence of SEQ ID NO: 113;

(b) a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 12;

(c) a nucleic acid molecule that selectively hybridizes to the nucleic acid molecule of (a) or (b) (see alignment above, where 20P2H8, which corresponds to SEQ ID NO:10 of Afar shares 85.7% similarity with the full length of SEQ ID NO:12); or

(d) a nucleic acid molecule having at least 95% sequence identity to the nucleic acid molecule of (a) or (b); or

(e) a polypeptide of claim 12.

Conclusion

No claims are allowed. All claims stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEPHANIE K. MUMMERT whose telephone number is (571)272-8503. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephanie K. Mummert/
Examiner, Art Unit 1637

SKM